ellman

Surgitron

FFPF EMC

Operating Manual

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WARNING

Ellman International strongly recommends
the use of the Ellman Corneal Eye Shields Cat# H781 for
any radiofrequency surgical procedure involving the eyelid
and the immediate surrounding areas.

INTRODUCTION

Surgery that is performed with modern radiosurgical equipment should not be confused with the results obtained with electrocautery, medical diathermy, spark- gap generators, or partially rectified devices that do not provide surgical cutting waveforms. Thus, before reviewing the instructions and clinical use, a brief definition of radiosurgery and of the radiofrequency waves that produce this phenomenon may prove helpful.

Radiosurgery is an atraumatic method of cutting and coagulating soft tissue, without the post-op pain and tissue destruction of electrocautery. The cutting effect, known as **electrosection**, is performed without manual pressure or crushing tissue cells. It results from heat generated by the resistance the tissues offer to the passage of a radiofrequency wave, which is applied with a fine wire called a surgical electrode. The heat disintegrates and volatilizes the cells in the path of the waves. This causes the tissue to split apart as though it had been cut with a razor-sharp knife. **Electrocoagulation** is a nonvolatilizing destruction of tissue cells by a radiofrequency wave.

The atraumatic nature of electrosection provides a noteworthy advantage. The lack of trauma results in tissue healing without fibrous contractile scar tissue, which characterizes healing of wounds created by manual cutting. An equally significant advantage is provided by the sterilizing effect of radiosurgery.

Radiosurgery, as a result of these advantages, facilitates, accelerates, and improves surgical procedures tremendously. It also helps to eliminate the unfavorable post-operative sequelae such as **pain, swelling, infection, trismus,** and **post-surgical shock** from excessive blood loss, that are so often experienced after “traditional” instrumentation for comparable surgery.

GENERAL DESCRIPTION

The Surgitron F.F.P.F. EMC has been investigated and acknowledged for compliance with EMC Directive in accordance with the following listed standards by an independent testing laboratory.

1. Comforms to the immunity requirements of: EN 60601-1-2.
2. Comforms to the emissions requirements of: EN 60601-1-2

SAFETY AND WARNINGS

- Improper use of this, or any electrosurgical instrument, can result in a patient injury. Read and become familiar with all instructions and directions before using this product and all electrosurgical devices. Refer to the Operator's Manual of your electrosurgical generator for proper set-up and use. Follow all manufacturer's guidelines for electrosurgical safety.
- Make sure the proper electrosurgical ground pad is used, following the manufacturer directions for proper placement and application.
- Use the proper output setting as recommended by the manufacturer for the specific procedure being performed.
- When not in use, electrosurgical instruments should be placed in a suitable holder or site which will prevent flow of current to the patient, or the surgical drapes, should the operator accidentally activate the electrosurgical generator.
- Always use the lowest possible power setting to achieve the desired electrosurgical effect.
- Do not activate the electrosurgical unit until the tip of the instrument is touching the target tissue, or in very close prox imity to it in the instance of fulguration spray coagulation.
- Do not activate the electrosurgical unit if you cannot clearly see the position of the instrument tip with respect to all surrounding tissues and structures.
- Do not activate the electrosurgical instrument if the tip of the instrument is within the trocar cannula.
- Do not simultaneously activate the electrosurgical generator while irrigating through the instrument.
- Do not coil or loop electrosurgical cables or hang a looped cable on a metal object such as the OR table or an IV pole.
- Do not use these instruments with a cable that does not make good, secure contact with the electrosurgical adapter of the instrument or the electrosurgical generator.If in doubt about the compatibility of a cable from another manufacturer, use the cable provided with this instrument or check with your hospital Biomedical Engineer.
- Prior to surgery, patient should be checked for internal body gases prior to the use of any electrosurgical electrodes.

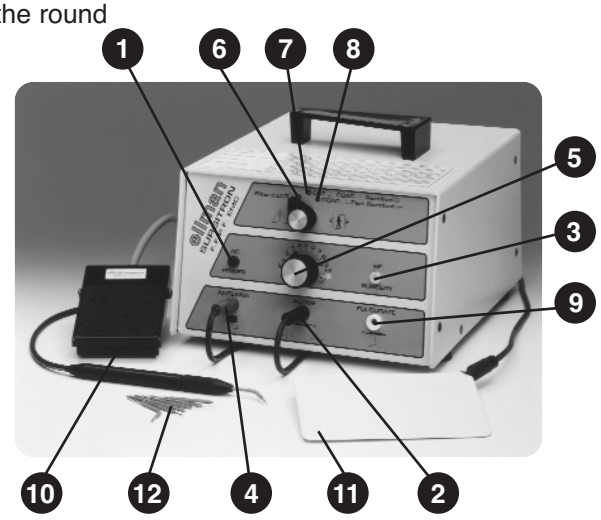
INTENDED USE

Cutting
skin incisions, biopsy, cysts, abscesses, tumors, cosmetic repairs, development of skin flaps, skin tags, nevi, keratosis, oculoplastic procedures, blepharoplasty, aponeurotic repair, levator resection.
Blended Cutting and Coagulation
skin tags, papilloma keloids, keratosis, verrucae, basal cell carcinoma, nevi, skin tags, fistulas, epithelioma, cosmetic repairs, cysts, abscesses, development of skin flaps, oculoplastic procedures.
Hemostasis
control of bleeding, epilation, telangiectasia.
Fulguration
basal cell carcinoma, papilloma, cyst destruction, tumors, verrucae, hemostasis.
Bipolar
pinpoint, precise coagulation. Pinpoint hemostasis in any field; wet or dry.

GENERAL INFORMATION

OPERATIONAL FUNCTIONS OF SURGITRON F.F.P.F. EMC

1. **Power switch** is located in the rear panel. When power switch is turned on, the AC green light indicator should be on.
2. **Active (Black)** - Surgitron handpiece plugs into this color-coded jack.
3. **R.F. (White) Indicator Light** - Signals when electrode is being activated. Foot pedal or Fingerswitch must be depressed.
4. **Antenna Plate** - (Green) Recommended for all surgical and coagulation procedures. The Antenna (Indifferent) Plate is inserted into this jack.
5. **Variable Power Control Dial** - Sets desired power output by fine tuning. (see Pre-Operative Cutting Practice on page 6).
6. **Cut (Filter)** - Setting for cutting waveform with minimal coagulation
7. **Cut & Coagulation (Fully Rectified)** - Setting for cutting and coagulation simultaneously
8. **Coagulation (Partially Rectified)** - Setting for extra bleeding hemostasis waveform.
9. **Fulguration** - Insert "black" Surgitron F.F.P.F. EMC Handpiece from "black" Active terminal to "white" Fulgurate terminal. Turn the upper waveform dial to "Partially Rectified." Turn the round power dial to 6 or 7. If a more controlled spark is desired, power dial may be lowered based on desired result.
10. **Foot Switch Assembly**
11. **Antenna Assembly**
12. **Electrode Set**



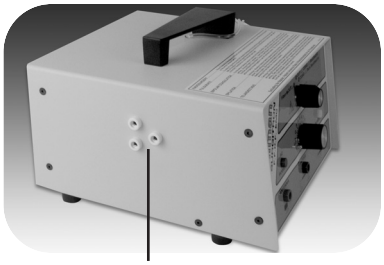
SPECIFICATIONS
ellman Surgitron F.F.P.F. EMC (World Patents)

Model:
Surgitron F.F.P.F. EMC (220 ~ 240 volts)
Output Voltage - Variable from 500 to 600 +/- 20%
Output Power - 140 +/- 20%
Output Frequency - 3.8 MHz.
Output Waveform -
Cut (Fully Filtered)
Cut & Coag (Fully Rectified)
Coag (Partially Rectified)
Fulguration (Spark-Gap)

Part Number
EMC110 or similar
HP1
S10 or Similar
H4
EK22
EMCL1

Size:
Width - 8 inches
Height - 6 1/4 inches
Depth - 9 inches
Net Weight - 9 1/4 lbs

CONTENTS
1 - Surgitron F.F.P.F. EMC
Radiosurgical Instrument with Foot Switch Assembly
1 - Radiosurgery Autoclavable Handpiece & Cord
1 - Set of Autoclavable Electrodes
1 - Antenna Plate
1 - EMC RF Power Cord
1 - Instruction Manual



Universal Fingerswitch Adapter
(sold separately) connectors

PREPARATION FOR USE

PREPARATION OF SURGITRON F.F.P.F. EMC

Be sure that the power switch is in the OFF position. Connect the **ellman** Hospital Grade plug to AC power receptacle. Insert the Handpiece male plug into the **black** female jack on the front panel of the Surgitron F.F.P.F. EMC marked "Handpiece". Insert the Antenna Plate male plug (green) into the **green** female jack on the front panel marked "Antenna Plate". The Antenna Plate should be placed on the operating table positioned near the operative site. The Antenna Plate does not have to make skin contact, but should be under the patient. Select the correct electrode for the particular procedure to be performed. Insert the selected electrode into the Handpiece. Make sure that the electrode is seated fully in the Handpiece so that no brass is exposed, and secure tightly.

OPERATIONAL PREPARATION OF SURGITRON F.F.P.F. EMC

1. Turn on the power switch at the back of unit. Allow 15 seconds warm up before activating.
2. Switch the waveform selection dial to Filtered Cut for pure micro-smooth cutting.
3. For cutting with coagulation, switch the waveform selection dial to Cut & Coag Fully Rectified.
4. For pure Hemostasis-Coagulation to control all forms of hemorrhage, switch the waveform selection to Coag-Partially Rectified.
5. Fulguration - Remove handpiece jack from black terminal marked "Handpiece" and place into white terminal marked "Fulgurate." Turn the upper waveform dial to "Coag-Partially Rectified." Fulgurate Spark-Gap for dessication will be Produced.

CLINICAL INFORMATION AND PRACTICING PROCEDURES

LEARNING TO USE RADIOSURGERY

Before making contact with the tissue, the power intensity must be selected and the foot switch must be activated. During the actual cutting, it is important to use a smooth uninterrupted motion with even and light pressure. The movement should not be too slow. If it is, the build-up of lateral heat in the tissue may cause charring, followed by necrosis and sloughing. (see Pre-operative Cutting Practice). When performing a second or third cut in the same surgical site, allow approximately ten seconds for the tissue to cool or use cool water, saline, or air spray between applications of the electrode to the site. Radiosurgery should not be regarded as a totally new art that will require learning of old skills. All rules of good surgical technique and clinical judgment still apply. The biggest difference, and **the most important thing to be learned,** is that radiosurgery cuts **without pressure,** unlike the steel scalpel, and so a light, smooth, continuous brush-like stroke should be developed. Only then will the surgeon really appreciate the tremendous advantages inherent in radiosurgery.

Defining Good Technique

Almost the only way that radiosurgery can create tissue damage is if heat is allowed to accumulate in the tissue to the point where excessive dehydration occurs and the tissue is destroyed. Preventing the accumulation of such heat is the basic objective of electrosurgical technique. The accumulation of lateral heat in tissue depends upon various factors as indicated in the following formula:

$$\text{Lateral Heat} = \frac{\text{Time Which Electrode Contacts Tissue} \times \text{Intensity of Power} \times \text{Electrode Size} \times \text{Nature of Wave}}{\text{Frequency}}$$

Note: Unit duty cycle is 10 seconds ON, 30 seconds OFF for 30 surical procedures, followed by a 5 minute. Damage to the Suritron may result if not followed closely.

This formula may be broken down in the following manner:

Electrode Contact Time

a. The slower the passage of the electrode, the greater the lateral heat.
b. The more rapid the passage of the electrode, the less the lateral heat.

Intensity of Power

a. Intensity too high = high accumulation of lateral heat, due to sparking.
b. Intensity correct = lateral heat reduced to the minimum necessary to volatilize tissue cells. Smooth flow through tissue with no sparking and no resistance through tissue.
c. Intensity insufficient = high accumulation of lateral heat due to drag. Also excess bleeding due to tissue being pulled and torn from its base.

Electrode Size

a. The larger the electrode, the more lateral heat produced and the higher the power setting necessary to operate.
b. The smaller the electrode, the less lateral heat produced and the lower the power setting necessary to operate.

Nature of the Waveform

a. Fully Rectified Filtered = Least lateral heat.
b. Fully Rectified = Less lateral heat.
c. Partially Rectified = High lateral heat.

Frequency - The higher the frequency, the less lateral heat produced. The Surgitron has a frequency output of 3.8 - 4.0 MHz. This is the optimum frequency as shown in clinical studies.

RADIOSURGICAL WAVEFORM

Radiosurgery has many practical uses in surgery. Surgitron instrument has the ability to control bleeding by coagulation, which can be limited to just the surface area where it is needed, without heavy and deep tissue destruction. This conserves tissue and reduces trauma, and makes the use of escharotics like silver nitrate, potassium permanganate, and iodine crystals seem barbaric. Approximately 75% of all clinical radiosurgery procedures are performed with the cutting waveforms:

1. Continuous Wave - Fully Filtered
2. Modulated Wave - Fully Rectified

FULLY FILTERED WAVE

The Fully Filtered Waveform is a pure continuous flow of high frequency waves. This filtration results in a continuous non-pulsating flow of waves which provides a micro-smooth cutting flow. Under many clinical conditions this feature is most advantageous. This wave produces the least amount of lateral heat and tissue destruction.

FULLY RECTIFIED WAVE

The Fully Rectified Waveform produces a minute but perceptible pulsating effect which can, under certain conditions, slightly reduce the efficiency of the cutting effect.

In addition to a smooth cut, the Fully Rectified Wave is accompanied by a very slight superficial coagulation on the tissue surfaces. This coagulation is imperceptible clinically and microscopically, yet it provides effective hemostasis.

When the tissue is areolar, a perceptible film of coagulum forms along the surface of the coated margins as the tissue heals. The coagulum does not interfere with normal healing by primary intention, and peels off spontaneously when the healing is complete.

PARTIALLY RECTIFIED WAVE

The Partially Rectified Waveform is an intermittent flow of the high frequency waves producing hemostasis and is highly effective in sealing off bleeders up to a 1/16 inch in diameter, eliminating the need to tie them off. The Partially Rectified Wave is also recommended for the indirect technique where one can coagulate blood vessels by grasping a hemostat and lifting free of surrounding tissues. An electrode is then brought into contact with the hemostat, 1 or 2 inches from its tips. When the Partially Rectified Waveform is turned on, the walls of the vessel will be sealed making ligation unnecessary, in most cases.

FULGURATION

The Fulguration or Spark-Gap Wave is a mutated electronic current that has been weakened to simulate the effects of the Oudin current. The Fulguration current produces a potent dehydrating effect on tissues. Its destructiveness is self-limiting because of the air space the sparks must jump and because of the insulating effect of the carbon or eschar and the movement to prevent cumulative heat destruction.
Insert "black" Surgitron F.F.P.F. EMC Handpiece from "black" Active terminal to "white" Fulgurate terminal. Turn the upper waveform dial to "Partially Rectified." Turn the round power dial to 6 or 7. If a more controlled spark is desired, power dial may be lowered based on desired result.

GENERAL DESCRIPTION

The **ellman** Surgitron F.F.P.F. EMC is used to cut, cut and coagulate, coagulate extra-heavy bleeding, and fulgurate. Special modes are provided for each of these functions.

PRECAUTIONS

1. Radiosurgery **should not** be used by anyone who wears a pacemaker without first consulting the physician to insure that the pacemaker is protected and not affected by high frequency interference.
2. The radiosurgical instrument **should not** be used in the presence of flammable or explosive liquids or gases.
3. Remember to deactivate the Handpiece, by removing foot from Foot Pedal, each time an electrode is changed.
4. If the radiosurgery unit is not used for a period of time or if proper settings are not known, the operator should start off with a low power setting and cautiously increase power until ideal cut is accomplished with no tissue drag and minimum sparking.
5. Due to radiofrequency from radiosurgery, place the ECG monitoring electrode as far away as possible from the radiosurgery Antenna Plate.

ANESTHESIA

Anesthesia, either local or general, must be used with radiosurgical procedures. IF NITROUS OXIDE analgesia is used, a local anesthetic should also be used.

CUTTING

Since radiosurgery requires virtually no pressure to effect a cutting action, the hand should rest on some support in order to retain good control over the instrument. The ingredients for efficient radiosurgery are a gentle touch, digital dexterity, a fluid wrist action, and a feather-light touch. **The tissue to be cut should be moist. If it is too dry, surface charring will occur. Excessively dry tissue can most easily be moistened with a wet gauze.** Prior to performing an operative procedure, the area should be studied in order to select the correct electrode, waveform and power. Several practice strokes, with power off, are recommended to determine the correct length, depth, and direction of cut.

PRE-OPERATIVE CUTTING PRACTICE

Prepare the Surgitron F.F.P.F. EMC for operations as described in PREPARATION FOR USE, then follow the steps below.

1. Select a piece of fresh, lean beef containing very little fat. **Do not** use veal because it does not change color when cut with an electrode. Allow meat to reach room temperature.
2. Place the meat on the Antenna Plate.
3. Insert the electrode of choice (Vari-Tip, Diamond or Loop) into the handpiece.
4. Rotate the Power Output knob to the #8 position.
5. Turn the waveform dial to the Filtered Cut position.
6. Depress the foot switch.
7. Using a smooth, brush-like motion, make several incisions of various lengths and depths. Then de-energize the electrode and observe the results. You will note that the power setting has been too high, causing sparking and noticeable discoloration along the cutting track.
8. Reduce the Output Power intensity to the #1 position. You will notice the electrode either will not cut at all, or it will cut only with some pulling and dragging. Note if cutting does occur, tissue shreds adhere to the electrode.
9. Repeat the above procedure for Output Power Intensity settings of #6, #5, etc., until such point when no discoloration occurs and there is no visible sparking. The radiosurgical tip should not encounter resistance. The cut should be microsmooth without sparking and without drag. These results normally occur at an output power of #2 to #4. When the correct power setting is located, a magic marker can be used to indicate proper setting. **Continue to practice using slow, medium, and fast cutting strokes at each of the settings to acquire dexterity and confidence required for an actual operation on a patient.**

COAGULATION

The Surgitron can be used to seal off small blood vessels. Turn to the Partially Rectified Wave. The Ball electrode is normally used since it provides extended coverage of the tissue surfaces. Prior to performing coagulation, the tissue should be wiped clean of blood so that the area needing treatment can be viewed. Direct pressure will help to locate bleeders. Intermittent **gentle** contact with the tissue is performed until bleeding stops.

Important

Do not use the electrode to apply pressure to the bleeding site. This will prevent the radiowaves escaping from the electrode, therefore, no hemostasis will occur.

BIPOLAR

The Surgitron can be used for bipolar procedures by placing the (optional) Bipolar Cord plugs into Antenna and Active ports. The Waveform dial should be placed in the Coag-Partially Rectified position. The Power dial should be lowered to #1 or #2 depending on the procedure.

PRE-OPERATIVE COAGULATION PRACTICE

Prepare the Surgitron. The same meat specimen used for cutting may be used for coagulating practice. Effective coagulation is achieved when the treated area appears on the meat as blanched spot of approximately 2mm diameter with a minimum penetration into the tissue. Feather-light touching of the ball electrode is all that is necessary to coagulate bleeders efficiently.

1. Place the beef on the Antenna Plate.
2. Insert the ball electrode into the Handpiece.
3. Rotate the power dial to #1 position.
4. On the Surgitron F.F.P.F. EMC switch the dial to Partially Rectified-Coag.
5. Position the ball electrode in **very light** contact with the beef.
6. Depress the Foot Switch.
7. Repeat the above procedure with power settings of #2, #3, and #4. Contact should be 2 to 3 seconds.

CONTROL OF BLEEDING

Abnormal bleeding is not a problem in radiosurgery. A wide range of coagulation or hemorrhage control can be obtained by utilizing the Partially Rectified wave with different techniques. Coagulation can prevent bleeding or hemorrhage at the initial entry into soft tissue once blood is present. All forms of hemorrhage must be stopped first by some form of direct pressure - air, compression, or hemostat. When bleeding has momentarily stopped, final sealing of the capillaries or large vessels can be accomplished by short application of the Partially Rectified Coag Wave. There are two types of coagulation electrodes: ball electrodes and blade electrodes.

HANDPIECE AND ELECTRODE STERILIZATION

The active part of the electrode is always sterile when the Surgitron is in operative use. The tissue will also be sterilized when it comes in contact with the active electrode. This is an extreme advantage over the scalpel, which is contaminated by the nonsterile tissue surrounding the surgical incision. The shaft of the electrode, however, is not sterilized when the Surgitron is activated. It is suggested to autoclave the electrodes. Do not attempt to use the electrodes if the protective rubber housing is cracked or worn. In the event that the brass is exposed, a shock or burn may be felt by the operator or patient.

Note: Disposable electrodes are available.

AUTOCLAVING INSTRUCTIONS

The handpieces and electrodes can be **steam** autoclaved to a maximum temperature of 121°C (250°F) for a cycle of 20 minutes.

Refer to product inserts information for complete autoclaving information.

Note: To guarantee against cross contamination. **ellman** international highly recommends the use of disposable electrodes.

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